

REMARKS

Claims 1, 4-8 and 10-19 are pending in the current application. No new matter has been added. Claims 1 and 13 have been amended. Support for these amendments can be found in the published specification at paragraphs 48, 49, and 60-64 and Tables 1-3 under Examples 1 and 6. No new matter has been added by way of amendment. The present response is an earnest effort to place all claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

I. Detailed Action

Applicant acknowledges that the finality of the previous office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant further acknowledges that the Information Disclosure Statement (IDS) filed on April 18, 2005 has been considered and signed by the Examiner.

II. Rejections Maintained Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-8 and 10-19 have been rejected as new matter under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specifications in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record. As outlined previously, claim 1 recites the limitation "said SRF's are not bactericidal proteins or peptides". As outlined previously, this phrase does not appear in the specification, or original claims as filed. Moreover, Applicant does not point out specific basis for this limitation in the application, and none is apparent. The Examiner writes therefore this limitation is new matter.

This rejection is respectfully traversed. As amended, claim 1 now recites "quantifying an amount of SRFs present in said filtrate by determining an absorbance at a wavelength of 254 nanometers (nm)". This is not new matter as support for this amendment can be found in the published specification, at paragraphs 60 and 49, where paragraph 49 provides "Since the ultraviolet spectrum of the composite of SRFs indicates a maximum of 254 nm, the absorbency at 254 nm can be used to monitor their release." In addition, Applicant shows by example the quantification of the SRF's in the filtrate subsequent to the SRFs being released from the bacteria.

Applicant respectfully directs the Examiner's attention to Example 2 in the Published Specification. Example 2, paragraph 61 in the Published Specification, describes that "[t]he supernatant was collected by centrifugation and sterilized by passing through a 0.22 μ m filter. The <10 kDa SRFs were obtained by passing the sterile supernatant through a filter with a molecular weight cutoff of 10,000. Typically, the A_{254} of the <10 kDa fraction was 75 to 90% of the total supernatant." Additional examples of quantifying SRF's following their release and filtration can be found in the Published Specification, specifically, Examples 3-5, at paragraphs 62-64. Accordingly, the Specification provides a written description of amended claim 1 containing the additional limitation "quantifying an amount of SRFs present in said filtrate by determining an absorbance at a wavelength of 254 nanometers (nm)" and the dependent claims 4-8 and 10-19.

Accordingly, Applicant submits the 35 U.S.C. § 112, first paragraph rejection based on the amendment presented above has been overcome. Therefore, Applicant respectfully requests that this rejection be withdrawn and submits that claims 1, 4-8 and 10-19 are allowable.

III. Rejections Under 35 U.S.C. § 112, First Paragraph

Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record. The Examiner writes that the limitation "concentration of about 1000 to 50,000 AU of said stress response product/ml, corresponding to a reading at 254 nm in the UV range of light wherein the concentration of the stress response factors gives an Optical Density of 1.0 to 5.0.". The Examiner writes that this phrase does not appear in the specification, or original claims as filed. Moreover, the Examiner writes that Applicants do not point out specific basis for this limitation in the application, and none is apparent. The Examiner writes that nowhere in the specification is a correlation between product concentration and recited O.D. range.

Applicant respectfully traverses this rejection. As amended, claim 13 recites "administering the amount of SRFs from about 1000 to 24,000 AU of said SRFs/mL as determined at a wavelength of 254 nanometers." This is not new matter. Support for these

amendments can be found in the published specification at paragraph 48, Tables 1 and 3 under Examples 1 and 6, and Examples 3-5 at paragraphs 62-64.

The written description standard as applied to this application is improper. As stated: "[a]dequate description ... does not require the literal support for the claimed invention... Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skills in the art that an appellant had possession of the concept of what is claimed." *In Staehelin v. Secher*, 24 USPQ 2d 1513 (BPAI 1992). One skilled in the art would be familiar with and be able to determine "absorbance" or "A" and "optical density" or "O.D." prior to Applicant's filing date.

Furthermore, one skilled in the art would be able to determine based on the instant Specification absorbance (A), optical density (O.D.), or arbitrary units (AU) for SRFs. In contrast to the Examiner's statement, Applicant submits that the Specification provides sufficient written description of absorbance (A), optical density (O.D.), and arbitrary units (AU).

The published specification discloses and describes the relationship between absorbance and optical density at paragraph 49 which provides: "Since the ultraviolet spectrum of the composite of SRFs indicates a maximum of 254 nm, the absorbency at 254 nm can be used to monitor their release. One Arbitrary Unit (AU) of SRFs was established as that level providing an optical density of 0.001 through 1 cm. of a solution." From this definition in the specification, $1 \text{ AU} = \text{O.D.}/\text{pathlength}$, specifically, $1 \text{ AU} = 0.001 \text{ O.D.}/1 \text{ cm pathlength}$ or $\text{O.D.} = 1000 \text{ AU/cm}$.

It was well known prior to Applicant's filing date that O.D. and A may be calculated from the following equation or formula: $\text{O.D.} = (A * V) / p$, wherein where A is the absorbance at a particular wavelength measured in nanometers, V is the solution volume in mL, and p is the length of the light path through the sample (cm). Applicants have submitted for Examiner's consideration a copy of a published reference in the public domain prior to Applicant's earliest filing date of May 11, 1993 that discloses the relationship between A and O.D. Fruton, JS and Simmonds, S. *GENERAL BIOCHEMISTRY* 71-72 (Academic Press, John Wiley and Sons) 1953. (See Information Disclosure Statement (IDS) submitted April 18, 2005). Furthermore, it is common knowledge that when the spectrophotometer has a path length of 1 cm, absorbance = optical density (O.D.).

Thus, substituting $O.D. = 1000 \text{ AU/cm}$ into the equation $O.D. = (A * V) / p$, $1000 \text{ AU/cm} = (A * V) / p$. Replacing the pathlength variable p with 1 cm as provided in the Specification at paragraph 49, $1000 \text{ AU/cm} = (A_{254} * V) / 1 \text{ cm}$. Next, volume is measured in mL so the equation becomes $1000 \text{ AU/cm} = (A_{254} * \text{mL}) / 1 \text{ cm}$. Multiplying by 1 cm to remove the denominators, $1 \text{ cm} * 1000 \text{ AU/cm} = (A_{254} * \text{mL}) / \text{cm} * 1 \text{ cm}$, we are left with $1000 \text{ AU} = A * \text{mL}$. Thus, providing the relationship that $A_{254} = 1000 \text{ AU/mL}$ or in other words, A_{254} equals $1000 \text{ Arbitrary Units/mL}$.

Applicant teaches the relationship between optical density and absorbance as provided by paragraph 49 in the published specification and as demonstrated in the Examples section, specifically Examples 3-5 in the published specification. For example, Example 4, at paragraph 63, provides "*E. coli* was propagated in Minimal-Media-Davis (MMD) as described in Example 1 to yield a $<10 \text{ kDa}$ fraction of SRFs with an $A_{254} = 8.000$ or 8000 AU/mL ." One skilled in the art would be familiar with and able to use such equations to determine absorbance at a wavelength of 254 nm and AU as the Applicant has done.

Therefore, contrary to the Examiner's assertion that this limitation is new matter, that no specific basis for this limitation in the application exists, and that none is apparent, Applicant has specifically disclosed the relationship between O.D. and Arbitrary Units (AU), as well as the relationship between A_{254} and AU from specific examples. Data from Tables 1 and 3 from Examples 1 and 6 respectively in the published specification support the ranges found in the amended claims. No new matter has been added.

Applicant respectfully disagrees that those of skill in the art would not know how to determine the amount of SRFs in a filtrate as described by the Applicant. Applicant submits that the subject matter, "administering the amount of SRFs from about 1000 to $24,000 \text{ AU}$ of said SRFs/mL as determined at a wavelength of 254 nanometers " is described sufficiently so as to convey to one of skill in the art that Applicant had possession of the claimed invention. Thus, Applicant is in compliance with the written description requirement.

In light of the above, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph to claim 13 be withdrawn and reconsidered.

IV. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner writes that claim 13 recites the limitation "stress response factors" in line 4 and that there is insufficient antecedent basis for this matter in the claim.

Although not acceding to the Examiner's rejection, in an effort to expedite prosecution Applicant has now amended claim 1 so that it now recites "separating said medium and SRFs from said bacteria to form a separated product". Support for this amendment can be found in the published specification at paragraph 48. Claim 13 has been similarly amended to recite "administering the amount of SRFs from about 1000 to 24,000 AU of said SRFs/mL as determined at a wavelength of 254 nanometers". Support for this amendment can be found in paragraph 48, and Tables 1 and 3 in the Published Specification, under Examples 1 and 6.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claim 13 under 35 U.S.C. § 112, second paragraph.


V. Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,


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